



NDA 19-414 / S-021

## SUPPLEMENT APPROVAL

Bracco Diagnostics Inc.  
Attention: Melanie Benson  
Director, US Regulatory Operations  
259 Prospect Plains Rd, Building H  
Monroe Township, NJ 08831

Dear Ms. Benson:

Please refer to your supplemental new drug application (sNDA) dated July 31, 2018, received July 31, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cardiogen-82 (Rubidium Rb 82 Generator).

We acknowledge receipt of your amendment dated April 15, 2020, which constituted a complete response to our May 31, 2019, action letter.

This Prior Approval supplemental new drug application provides additional supplemental data supporting the use of the CardioGen Generator with the new CardioGen-82 Infusion System Model 1700. The new infusion system features technology to identify radionuclides in the generator eluate and cessation mechanisms to prevent patient administration if excess undesirable radionuclides are detected.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **CARTON AND CONTAINER LABELING**

We acknowledge your September 30, 2020, submission containing final printed carton and container labeling.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.<sup>3</sup>

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR

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<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

<sup>3</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> [http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf4\\_Subpart B](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf4_Subpart_B).

<sup>6</sup> Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, contact Sharon Thomas, Regulatory Project Manager, at 301-796-1994

Sincerely,

*{See appended electronic signature page}*

Libero Marzella, M.D., Ph.D.  
Director  
Division of Imaging and Radiation Medicine  
Office of Specialty Medicine  
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
- Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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